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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/519,238 | 08/01/2005 | Richard Hale | 232432 | 4832 |
| 23460 | 7590 | 09/08/2006 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD | | | | WANG, CHANG YU |
| TWO PRUDENTIAL PLAZA, SUITE 4900 | | | | |
| 180 NORTH STETSON AVENUE | | | | |
| CHICAGO, IL 60601-6780 | | | | |
| | | | | ART UNIT |
| | | | | PAPER NUMBER |
| | | | | 1649 |

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/519,238 | HALE ET AL. | |
| | Examiner | Art Unit | |
| | Chang-Yu Wang | 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 15-20, 44, drawn to a protein complex comprising sambiasin-1/2 and presenilin-1/2/nicastrin.

Group II, claim(s) 9, 10, 43, 46, 48 drawn to a protein comprising SEQ ID NO:1, an array comprising SEQ ID NO:1 and a pharmaceutical composition comprising SEQ ID NO:1.

Group III, claim(s) 11-13, drawn to a DNA encoding SEQ ID NO:1 and host cell comprising SEQ ID NO:1.

Group IV, claim(s) 14, 47, drawn to an antibody binding to the protein complex of claim 1 and an array comprising the antibody.

Group V, claim(s) 18, drawn to a method for processing the physiological substrate of the protein complex of claim 1.

Group VI, claim(s) 21-28, 49, drawn to a method of screening for a molecule that binds to/modulates the complex of claim 1 or SEQ ID NO:1.

Group VII, claim(s) 29 and 30, drawn to a method of manufacturing a medicament that modulates the activity of the protein complex of claim 1.

Group VIII, claim(s) 31-37, drawn to a method for diagnosing/screening for the presence of a disease that is characterized by an aberrant activity of the protein complex of claim 1.

Group IX, claim(s) 38-40, drawn to a method for treating/preventing a disease characterized by an aberrant activity of the protein complex of claim 1.

Group X, claim(s) 42, drawn to an antibody against SEQ ID NO:1.

Group XI, claim(s) 45, drawn to a kit comprising the complex of claim 1 and an antibody binding to the complex.

2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The 1st claimed invention is drawn to a protein complex comprising sambiasin-1/2 and presenilin-1/2/nicastrin. Since presenilin-1/2/nicastrin is known in the art and as stated by Applicant on p.2 of the specification, the 1st claimed invention is found to have no special technical feature that defined the contribution over the prior art. Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions they do not have a single inventive concept and so lack unity of invention.

In addition, the inventions V-IX do not share a common corresponding technical feature as they comprise distinct steps and results and utilize different products, which demonstrate that each method has a different mode of operation. The effects and

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outcomes of each invention also are very divergent. The inventions I-IV, X and XI do not have a single inventive concept as they use different molecules.

Group I is drawn to a technical feature of a protein complex comprising sambiasin-1/2 and presenilin-1/2/nicastrin.

Group II is drawn to a technical feature of a protein comprising SEQ ID NO:1, an array comprising SEQ ID NO:1 and a pharmaceutical composition comprising SEQ ID NO:1.

Group III is drawn to a technical feature of a DNA encoding SEQ ID NO:1 and host cell comprising SEQ ID NO:1.

Group IV is drawn to a technical feature of an antibody binding to the protein complex of claim 1 and an array comprising the antibody.

Group V is drawn to a technical feature of a method for processing the physiological substrate of the protein complex of claim 1.

Group VI is drawn to a technical feature of a method of screening for a molecule that binds to/modulates the complex of claim 1 or SEQ ID NO:1.

Group VII is drawn to a technical feature of a method of manufacturing a medicament that modulates the activity of the protein complex of claim 1.

Group VIII is drawn to a technical feature of a method for diagnosing/screening for the presence of a disease that is characterized by an aberrant activity of the protein complex of claim 1.

Group IX is drawn to a technical feature of a method for treating/preventing a disease characterized by an aberrant activity of the protein complex of claim 1.

Group X is drawn to a technical feature of an antibody against SEQ ID NO:1.

Group XI is drawn to a technical feature of a kit comprising the complex of claim 1 and an antibody binding to the complex.

Accordingly, Groups I-XI are not so linked by the same or corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept. Thus, they do not have a single inventive concept and so lack unity of invention.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-XI as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

5. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

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7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
August 30, 2006



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER